

**ASSEMBLY BILL**

**No. 103**

**Introduced by Assembly Member Reyes**

January 10, 2003

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An act to add Section 4168 to the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as introduced, Reyes. Pharmaceuticals: marketing activities.

Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. Under the Pharmacy Law, all revenue collected by the board is deposited into the Pharmacy Board Contingent Fund. The Pharmacy Law makes a violation of its provisions punishable as a crime.

This bill would require a pharmaceutical manufacturing company, as defined, to annually disclose to the board economic benefits the company provides in connection with its marketing activities. The bill would also require the board to report annually to the Governor and the Legislature regarding these disclosures.

The bill would impose a civil penalty of \$10,000 for the violation of its disclosure requirements and would specify that awards obtained by the board be deposited into the Pharmacy Board Contingent Fund.

The bill by specifying an additional requirement under the Pharmacy Law, the violation of which is punishable as a criminal offense, would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4168 is added to the Business and  
2 Professions Code, to read:

3 4168. (a) On or before January 1 of each year, a  
4 pharmaceutical manufacturing company shall disclose to the  
5 board the value, nature, and purpose of any gift, fee, payment,  
6 subsidy, or other economic benefit it provided directly or through  
7 its pharmaceutical marketers in connection with detailing,  
8 promotional, or other marketing activities to a physician, hospital,  
9 nursing home, pharmacist, health benefit plan administrator, or  
10 any other person in California authorized to prescribe, dispense,  
11 or purchase dangerous drugs in this state. Disclosure shall be made  
12 on a form and in a manner prescribed by the board. The initial  
13 disclosure shall be made on or before January 1, 2005, for the  
14 period beginning on July 1, 2003, and ending June 30, 2004. The  
15 board shall report to the Governor and the Legislature on or before  
16 March 1 of each year, commencing in 2006, the information  
17 disclosed to it pursuant to this section.

18 (b) A pharmaceutical manufacturing company shall also  
19 disclose to the board, on or before October 1, 2004, and annually  
20 thereafter, the name and address of the individual responsible for  
21 the company's compliance with the provisions of this section.

22 (c) The board shall not disclose information identified as a  
23 trade secret by the pharmaceutical marketing company in its  
24 disclosure.

25 (d) The following shall be exempt from disclosure:

26 (1) A complimentary sample of a dangerous drug intended to  
27 be furnished to a patient.

28 (2) The payment of reasonable compensation and  
29 reimbursement of expenses in connection with a clinical trial.

(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars (\$25).

(4) A scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference of a national, regional, or specialty medical or other professional association, if the recipient of the scholarship or other support is selected by the association.

(e) A civil penalty in the amount of ten thousand dollars (\$10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty may be assessed. The prevailing plaintiff in the action shall be awarded costs and reasonable attorney's fees in addition to the civil penalty. If the board is the prevailing plaintiff, the civil penalty, costs, and attorney's fees shall be deposited into the Pharmacy Board Contingent Fund.

(f) The following definitions apply for purposes of this section:

(1) "Clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(2) "Pharmaceutical manufacturing company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly, or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical manufacturing company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.

(3) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a dangerous drug.

1 SEC. 2. No reimbursement is required by this act pursuant to  
2 Section 6 of Article XIII B of the California Constitution because  
3 the only costs that may be incurred by a local agency or school  
4 district will be incurred because this act creates a new crime or  
5 infraction, eliminates a crime or infraction, or changes the penalty  
6 for a crime or infraction, within the meaning of Section 17556 of  
7 the Government Code, or changes the definition of a crime within  
8 the meaning of Section 6 of Article XIII B of the California  
9 Constitution.

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